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DEPARTMENT OF HEALTH AND SENIOR SERVICES
DIVISION OF EPIDEMIOLOGY, ENVIRONMENTAL AND OCCUPATIONAL HEALTH
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CHRISTINE GRANT, J.D., M.B.A.
Commissioner

December 10, 1999

Mr. Larry D. Spears
Center for Devices and Radiological Health (HF2-340)
Food and Drug Administration
2094 Gaither Road
Rockville, MD 20850

Dear Mr. Spears:

This letter will serve as a comment to FDA's "proposed strategy on reuse of single-use devices." It is important that the FDA provide leadership and direction to industry and health care facilities on this issue. We believe this issue to be an important safety issue that will have a direct impact on the general public. Please accept the following comments in support of this monumental task.

1. Reconsider the agency's current policy on establishments that reprocess SUD's.

The New Jersey Department of Health and Senior Services (NJDHSS) has a licensure and inspection program for acute care facilities, ambulatory care facilities, and long term care facilities. We conduct licensure inspections once every two years. In 1990, we revised our state standards to include N.J.A.C. 8:43 G-8.4(f) which stipulates, "Single-use items shall be reused or reprocessed only if the manufacturer recommends reuse or reprocessing, or if the hospital has scientific validation of the safety of reprocessing and reuse of the item. Procedures for reprocessing and reuse shall conform with these recommendations or validation studies." Over the past ten years, reuse of single use devices in our acute care facilities has been a disaster. Not one hospital conducted a validation study to support reprocessing single use devices. A number of administrative orders were issued in order to stop unsafe practices.

The reasons why health care facilities did not comply with state standards are not clear. However, we believe that some reasons may include:

1. The costs associated for sterilization monitoring equipment and outside laboratory support are extremely high for each device reprocessed.

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2. The technical skills of central service personnel varies from hospital to hospital. Also, central service personnel lack experience in conducting this type of research.
3. There is tremendous pressure from hospital administrators to reduce costs, which has resulted in reprocessing without proper validation.

Needless to say, the Department is in the process of revising its state standards to specify the following.

8:43G-8.5 Single use medical devices and outsourcing.

(a) Single use patient care items shall be reprocessed under the following conditions:
   1. Only if the manufacturer provides written instruction for cleaning and sterilization of the item and the facility has the resources to meet those specifications and/or;
   2. Using the services of a third party reprocessor who possesses a certificate of registration with the Food and Drug Administration and has the following documentation to ensure compliance with quality systems regulations:
      i. Validation studies that demonstrate the efficacy of the sterilization process;
      ii. Studies to ensure the integrity of the item are not compromised for the number of reuses that can safely be performed;
   3. A quality control program shall be established to ensure the delivery of a safe product as specified in the contract with the third party processor.

The above standards will only allow reprocessing of a single use device in an acute care facility if the device is open and not used and the original manufacturer provides reprocessing specifications for this situation. All other situations will require a third party reprocessing registered by the FDA.

It is recommended that the FDA restrict SUD reprocessing to third party reprocessors with certain exemptions. It is important that the government control this issue by strict supervision of the industry. FDS's intention to collaborate with accredited third-party organizations or other federal agencies will dilute the effectiveness of your enforcement program. By allowing health care facilities to participate in reprocessing SUD's you not only dilute your agency's resources, but also you are using the hospital resources inappropriately. Third-party reprocessors will provide an economic benefit to the health care industry, by conducting validation studies for each device at a much lower cost than hospitals.

Hospital resources should be utilized to provide technical feedback from a user prospective. Utilizing the talents of the infection control professionals to design a study protocol central service professionals to evaluate packaging and handling and tracking

issues and OR personnel to comment on user issues and quality improvement personnel to identify patient issues would be a more effective use of our hospital resources.

An exemption from registration with FDA as a reprocessor should include hospitals that are reprocessing single use devices that are open and not in use and the manufacturer provides instructions for reprocessing. The second exemption would be shared reprocessing by multi-hospital reprocessing centers. There a number of health care facilities that have discontinued use of ETO after purchasing new technology. As a result, many institutions have found that certain devices can only be processed by ETO. Many institutions have decided to utilize hospitals that have existing ETO equipment. This may actually be a good use of resources within the industry. We are basically talking about reusable devices that have specific reprocessing parameters. Those facilities that maintain ETO systems must have licensed operators and comply with federal standards geared to protect employees. The Department has recently proposed the following rules regarding this issue.

8:43G8.5 Single use medical devices and outsourcing.

(b) Shared reprocessing by multi-hospital reprocessing centers shall meet the following standards.
1. Policies and procedures for all processing protocols shall be approved by all facilities in the network in conjunction with infection control and all sterile processing managers.
2. Instruments and devices transported off-site processing shall be inventoried and pre-cleaned prior to transportation.
   i. Soiled instruments shall be contained in impervious, closed containers, which are either locked or sealed in covered carts.
3. All decontamination, assembly and sterilization shall be preformed according to the device manufacturers written recommendations.
   i. Manufacturer's written instructions for processing of all specialty devices shall be obtained, followed and kept on file at the processing facility.
4. The following records shall be maintained at the processing facility.
   i. Sterilization logs shall be maintained for all items sterilized.
   ii. Biological monitoring as specified in 8:43G8.8(a).
   iii. Immediate notification shall be made to the receiving hospital upon a positive biological result.
5. Transport of sterile product shall be preformed using disinfected, impervious containers that are either locked or sealed in covered carts.

2. Explore the development of a device categorization system based on the level of risk presented by reprocessing and reusing SUDs and an enforcement strategy based on the level of risks.

This strategy has been suggested by number of health care professionals over the

years and does provide a practicable approach to the reuse problem. There are a number of issues that must be explored when implementing this strategy, for example:

Low Risk Reprocessed SUDs:

The number one issue when dealing with this category is to determine the appropriate number of reuses for each device. Clearly, the OEM is in the best position to make this determination. However, this would require a capital expenditure to conduct the appropriate validation studies and would result in a loss of revenue due to lost sales volume. This would require a regulatory incentive on the part of FDA in order for the OEM to participate in this endeavor.

The next logical choice is to standardize the number of reuses for each device based upon data collected from users. The data needed will be dependent upon the device and the method of reprocessing.

Moderate Risk Reprocessed SUDs:

This category appears to be a limbo category for SUD's. It may be better to clearly define the devices that would be considered moderate risk. This appears to be a step in the process rather than a category of risk for devices.

High Risk Reprocessed SUDs:

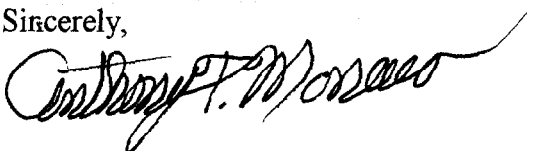
All pre-market requirements should be met for devices in this category.

4. **Consider requesting OEMs to provide information on their labels about risks associated with reuse of SUDs.**

Cautionary statements is an excellent idea to reinforce risk of reprocessing SUDs. This also will resolve concerns raised by health care providers regarding OEMs marketing practices of SUDs.

Thank you for the opportunity to comment and should you have any questions, please feel free to contact me at (609) 588-3124.

Sincerely,



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